DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2015

Medline Industries, Inc.
Mr. Matt Clausen
Senior Regulatory Affairs Specialist
One Medline Place
Mundelein, IL 60060

Re: K143147
Trade/Device Name: Gemini Bonded Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: April 15, 2015
Received: April 17, 2015

Dear Mr. Clausen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143147

Device Name
Gemini Bonded Sterilization Wrap

Indications for Use *(Describe)*
Gemini Bonded Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of such content for 180 days following sterilization. Gemini Bonded Sterilization Wrap is validated for use in steam or STERRAD® sterilization processes in the following sterilization modes and cycles.

• Pre-vacuum steam cycles
  * Minimum 4 Minutes Exposure at 270ºF/132ºC with minimum 20 minutes dry time

• Gravity steam cycles
  * Maximum 30 Minutes Exposure at 250ºF/121ºC with minimum 20 minutes dry time

• STERRAD® Sterilization
  * STERRAD® 100NX, Flex cycle
  * STERRAD® 100NX, Standard cycle
  * STERRAD® 100NX, Express cycle
  * STERRAD® 100S, Standard cycle
  * STERRAD® NX, Advanced cycle
  * STERRAD® NX, Standard cycle

The Gemini Bonded Sterilization Wrap intended loads with pre-vacuum steam sterilization, gravity steam sterilization, and the Advanced Sterilization Products (ASP) STERRAD® 100NX, STERRAD® 100S, and STERRAD® NX cycles are provided in Table 1.

The Gemini Bonded Sterilization Wrap Recommendations for Use with Pre-vacuum steam cycles, Gravity steam cycles, and the Advanced Sterilization Products STERRAD® Sterilization Systems are provide in Table 2.

(tables 1 and 2 are on a separate attachment. SEE ATTACHMENT)

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☑ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Number: K143147

Device Name: Gemini Bonded Sterilization Wrap

Table 1 – Validated Advanced Sterilization Products STERRAD® 100NX, STERRAD® 100S, and STERRAD® NX Cycles

Cycle	Maximum recommended Chamber Load		Intended Load
Pre-Vacuum Steam & Gravity Steam Cycles	Lightweight	6 lbs.	2 huck towels (17 in. x 29 in.), 3 fluid-resistant drapes (108 in. x 72 in.)
	Regular Weight	9 lbs.	16 huck towels (17 in. x 29 in.), 1 fluid resistant table cover (90 in. x 60 in.). 5 lbs. of metal mass.
	Medium Weight	13 lbs.	4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 11 lbs. of metal mass.
	Heavyweight	17 lbs.	4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 15 lbs. of metal mass.
	Super Heavyweight	25 lbs.	4 tray liners (20 in. x 25 in.) stacked 23in. x 11in. x 3.5 in. tray containing 20 lbs. of metal mass.
STERRAD® 100NX, Flex Cycle	10.7 lbs.		One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel- Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter. (A maximum of two flexible endoscope, one per tray per sterilization cycle.)
STERRAD® 100NX, Standard Cycle	10.7 lbs.		Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. (A maximum of two flexible endoscopes, one per tray per sterilization cycle.)
STERRAD® 100NX, EXPRESS Cycle	10.7 lbs.		Non-lumened reusable metal and non-metal devices requiring surface sterilization, and sterilization of diffusion-restricted spaces such as the hinged portions of forceps and scissors, and rigid or semi-rigid endoscopes without lumens.

STERRAD® 100S, Standard Cycle	Light Weight	6 lbs.	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter OF 2 mm or larger and length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless lumens. • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon/Polyethylene lumens.
	Regular Weight	10.7 lbs.	
	Medium Weight		
	Heavyweight		
	Super Heavyweight		
STERRAD® NX, Advanced Cycle	10.7 lbs.	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm of larger and a length of 500 mm or shorter of single-channel stainless steel lumens Or One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter.	
STERRAD® NX, Standard Cycle	10.7 lbs.	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm of larger and a length of 150 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.	

Table 2 – Wrap Model Recommendations for Use with Pre-vacuum steam cycles, Gravity steam cycles, and the Advanced Sterilization Products STERRAD® Sterilization Systems

Gemini Wrap Weight	**Item Number Series**	**Intended Load**	**Maximum Wrapped Package Content Weights Based on Validated Sterility Cycle**		
			Pre-Vacuum Steam & Gravity Steam	**Advanced Sterilization Products (ASP) STERRAD® 100S**	**Advanced Sterilization Products (ASP) STERRAD® NX and 100NX**
Light Weight	GEM11XX GEM11XXS	Light weight package (for example: standard linen	6 lbs	6 lbs	10.7 lbs

	GEM11XXT	packs)			
Regular Weight	GEM21XX GEM21XXS GEM21XXT	Light to moderate weight package (for example: general use medical instruments)	9 lbs	9.7 lbs	10.7 lbs
Medium Weight	GEM31XX GEM31XXS GEM31XXT	Moderate to heavy weight package (for example: general use medical instruments)	13 lbs	9.7 lbs	10.7 lbs
Heavyweight	GEM41XX GEM41XXS GEM41XXT	Heavyweight package (for example: general use medical instruments)	17 lbs	9.7 lbs	10.7 lbs
Super Heavyweight	GEM51XX GEM51XXS GEM51XXT	Very heavyweight package (for example: general use medical instruments)	25 lbs	9.7 lbs	10.7 lbs

The following loads were used in the pre-vacuum steam and gravity steam Sterility Validation Studies:

- Light Weight: 2 huck towels (17 in. x 29 in.), 3 fluid-resistant drapes (108 in. x 72 in.)
- Regular Weight: 16 huck towels (17 in. x 29 in.), 1 fluid resistant table cover (90 in. x 60 in.). 5 lbs of metal mass.
- Medium Weight: 4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 11 lbs of metal mass.
- Heavyweight: 4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 15 lbs of metal mass.
- Super Heavyweight: 4 tray liners (20 in. x 25 in.) stacked 23in. x 11in. x 3.5 in. tray containing 20 lbs of metal mass.

The following loads were used in the Advanced Sterilization Products (ASP) STERRAD® 100S Sterility Validation Studies:

- Light Weight: 15 in. x 10 in. x 1.2 in. tray containing metal instruments.
- Regular Weight: 15 in. x 10 in. x 1.2 in. tray containing metal instruments.
- Medium Weight: 15 in. x 10 in. x 1.2 in. tray containing metal instruments.
- Heavyweight: 15 in. x 10 in. x 1.2 in. tray containing metal instruments.
- Super Heavyweight: 15 in. x 10 in. x 1.2 in. tray containing metal instruments.

The following loads were used in the Advanced Sterilization Products (ASP) STERRAD® NX and STERRAD® 100NX Sterility Validation Studies:

- Light Weight: 23 in. x 11 in. x 4 in tray containing metal instruments.
- Regular Weight: 23 in. x 11 in. x 4 in tray containing metal instruments.
- Medium Weight: 23 in. x 11 in. x 4 in tray containing metal instruments.
- Heavyweight: 23 in. x 11 in. x 4 in tray containing metal instruments.
- Super Heavyweight: 23 in. x 11 in. x 4 in tray containing metal instruments.

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510(k) Summary (as required per 21 CFR 807.92)

Summary Preparation Date

May 7, 2015

Submitter / 510(k) Sponsor

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

Contact Person

Matt Clausen
Sr. Regulatory Affairs Specialist
Phone: 847-643-4785
Fax: 847-643-4482

Device Name / Classification

Device Name: Gemini Bonded Sterilization Wrap
Proprietary Name: Medline's Gemini Bonded Sterilization Wrap
Common Name: Sterilization Wrap
Classification Name: Sterilization Wrap (21 CRF 880.6850, product code – FRG)

Predicate Device

Gemini Sterilization Wrap - K113353

Device Description

Gemini Bonded Sterilization Wrap is comprised of two ply sheets ultrasonically bonded together for use by customers in accordance with standard hospital practices which require that two sheets are used each time a medical device or collections of medical devices are wrapped. The Gemini Bonded Sterilization Wrap provides the protection of double-wrapping in an efficient manner; reducing wrapping/unwrapping time significantly compared to traditional double-wrapping methods. Gemini Bonded Sterilization Wrap items are square or rectangular sheets of fabric produced using a five-layer SSMMS (spunbond-spunbond-meltblown-meltblown-spunbond) process. The standard blue wrap fabric is made of polypropylene with the addition of blue and white pigmentation. The wrap allows for aseptic opening of the sterilized package. The two-tone blue/pink wrap fabric is made of polypropylene with the addition of blue, white and red pigmentation. The wrap allows for aseptic opening of the sterilized package. Gemini sterilization wrap is available in sizes ranging from 12"x12" to 54"x72" across five different material weights/models.

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Indications for Use

Gemini Bonded Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until opened. Gemini Bonded Sterilization Wrap is validated for use in steam or STERRAD® sterilization processes in the following sterilization modes and cycles.

- Pre-vacuum steam cycles
  - Minimum 4 Minutes Exposure at 270ºF/132ºC with minimum 20 minutes dry time

- Gravity steam cycles
  - Maximum 30 Minutes Exposure at 250ºF/121ºC with minimum 20 minutes dry time

- STERRAD® Sterilization
  - STERRAD® 100NX, Flex cycle
  - STERRAD® 100NX, Standard cycle
  - STERRAD® 100NX, Express cycle
  - STERRAD® 100S, Standard cycle
  - STERRAD® NX, Advanced cycle
  - STERRAD® NX, Standard cycle

The Gemini Bonded Sterilization Wrap intended loads with pre-vacuum steam sterilization, gravity steam sterilization, and the Advanced Sterilization Products (ASP) STERRAD® 100NX, STERRAD® 100S, and STERRAD® NX cycles are provided in Table 1.

The Gemini Bonded Sterilization Wrap Recommendations for Use with Pre-vacuum steam cycles, Gravity steam cycles, and the Advanced Sterilization Products STERRAD® Sterilization Systems are provided in Table 2.

Medline Industries, Inc.
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Table 1 – Validated Advanced Sterilization Products STERRAD® 100NX, STERRAD® 100S, and STERRAD® NX Cycles

Cycle	Maximum recommended Chamber Load		Intended Load
Pre-Vacuum Steam & Gravity Steam Cycles	Lightweight	6 lbs.	2 huck towels (17 in. x 29 in.), 3 fluid-resistant drapes (108 in. x 72 in.)
	Regular Weight	9 lbs.	16 huck towels (17 in. x 29 in.), 1 fluid resistant table cover (90 in. x 60 in.). 5 lbs. of metal mass.
	Medium Weight	13 lbs.	4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 11 lbs. of metal mass.
	Heavyweight	17 lbs.	4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 15 lbs. of metal mass.
	Super Heavyweight	25 lbs.	4 tray liners (20 in. x 25 in.) stacked 23in. x 11in. x 3.5 in. tray containing 20 lbs. of metal mass.
STERRAD® 100NX, Flex Cycle	10.7 lbs.		One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel- Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter. (A maximum of two flexible endoscope, one per tray per sterilization cycle.)
STERRAD® 100NX, Standard Cycle	10.7 lbs.		Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. (A maximum of two flexible endoscopes, one per tray per sterilization cycle.)
STERRAD® 100NX, EXPRESS Cycle	10.7 lbs.		Non-lumened reusable metal and non-metal devices requiring surface sterilization, and sterilization of diffusion-restricted spaces such as the hinged portions of forceps and scissors, and rigid or semi-rigid endoscopes without lumens.
STERRAD® 100S, Standard Cycle	Light Weight	6 lbs.	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:
	Regular Weight	10.7	

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	Medium Weight Heavyweight Super Heavyweight	lbs.	• An inside diameter of 1mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter OF 2 mm or larger and length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless lumens. • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon/Polyethylene lumens.
STERRAD® NX, Advanced Cycle	10.7 lbs.	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm of larger and a length of 500 mm or shorter of single-channel stainless steel lumens Or One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter.	
STERRAD® NX, Standard Cycle	10.7 lbs.	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm of larger and a length of 150 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.	

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Table 2 – Wrap Model Recommendations for Use with Pre-vacuum steam cycles, Gravity steam cycles, and the Advanced Sterilization Products STERRAD® Sterilization Systems

Gemini Wrap Weight	**Item Number Series**	**Intended Load**	**Maximum Wrapped Package Content Weights Based on Validated Sterility Cycle**		
			Pre-Vacuum Steam & Gravity Steam	**Advanced Sterilization Products (ASP) STERRAD® 100S**	**Advanced Sterilization Products (ASP) STERRAD® NX and 100NX**
Light Weight	GEM11XX GEM11XXS GEM11XXT	Light weight package (for example: standard linen packs)	6 lbs	6 lbs	10.7 lbs
Regular Weight	GEM21XX GEM21XXS GEM21XXT	Light to moderate weight package (for example: general use medical instruments)	9 lbs	9.7 lbs	10.7 lbs
Medium Weight	GEM31XX GEM31XXS GEM31XXT	Moderate to heavy weight package (for example: general use medical instruments)	13 lbs	9.7 lbs	10.7 lbs
Heavyweight	GEM41XX GEM41XXS GEM41XXT	Heavyweight package (for example: general use medical instruments)	17 lbs	9.7 lbs	10.7 lbs
Super Heavyweight	GEM51XX GEM51XXS GEM51XXT	Very heavyweight package (for example: general use medical instruments)	25 lbs	9.7 lbs	10.7 lbs

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Summary of Technological Characteristics

Comparison of Subject and Predicate Devices

Characteristic	Subject Device	Predicate Device	Comparison
510(k)	TBD	K113353	n/a
Product Code	FRG	FRG	Same
Regulation No.	21 CRF 880.6850	21 CRF 880.6850	Same
Class	II	II	Same
Intended Use	Gemini Bonded Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of such content for 180 days following sterilization. Gemini Bonded Sterilization Wrap is validated for use in steam or STERRAD® sterilization processes.	Gemini Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of such content for 180 days following sterilization. Gemini Sterilization Wrap is validated for use in steam or STERRAD® sterilization processes.	Same
OTC / single use	Yes	Yes	Same
Device materials	Polypropylene w/ blue and pink pigmentation	Polypropylene w/ blue and pink pigmentation	Same
Device features	Square or rectangular sheets mfd. by spunbond-meltblown process	Square or rectangular sheets mfd. by spunbond-meltblown process	Same
Sizes	12”x12” to 54”x72”	12”x12” to 54”x72”	Same
Wrapping technique	Sequential/simultaneous double wrapping	Sequential/simultaneous double wrapping	Same
Bonding method	Ultrasonically seamed in a dotted line pattern along two sides	Unbonded	Different
Sterilization	- Pre-Vacuum Steam Cycle: 4 Minutes Exposure at 270°F/132C° with minimum 20 minutes dry time - Gravity Steam Cycle: 30	- Pre-Vacuum Steam Cycle: 4 Minutes Exposure at 270°F/132C° with minimum 20 minutes dry time - Gravity Steam Cycle: 30	Same

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	Minutes Exposure at 250°F/121°C with minimum 20 minutes dry time - STERRAD® 100NX (Flex, Standard, and Express Cycles) - STERRAD® 100S, Standard Cycle - STERRAD® NX (Advance and Standard Cycles)	Minutes Exposure at 250°F/121°C with minimum 20 minutes dry time - STERRAD® 100NX (Flex, Standard, and Express Cycles) - STERRAD® 100S, Standard Cycle - STERRAD® NX (Advance and Standard Cycles)	

This table illustrates the identical nature of the subject/predicate devices across all but one of the comparative features. The singular difference of ultrasonic bonding is the reason for this Special 510(k) submission.

Discussion of similarities and differences:

The proposed Gemini Bonded Sterilization Wrap is substantially equivalent in intended use, materials, device features / specifications and function in comparison to the predicate Gemini Sterilization Wrap. As noted in the table above, these characteristic comparisons render the devices identical. The difference between subject/predicate devices is related to:

- Bonding Method: The process involves the ultrasonic bonding on two single ply sheets of Gemini Sterilization Wrap. High-frequency ultrasonic acoustic vibrations and pressure fuse bond the layers together in a three-dotted line pattern along two open sides. There is no adhesive or other materials introduced to facilitate the bonding operation – strictly ultrasonic acoustic vibration and pressure.

Once the bonding process is completed, the predicate Gemini Wrap is converted into the proposed Gemini *Bonded* Wrap.

The following responses to FDA's 510(k) "Substantial Equivalence" Decision-Making Process (Overview) flow chart demonstrate substantial equivalence in terms of indications for use and technological characteristics.

Does the New Device Have the Same Intended Use?

Yes, the subject and predicate (K113353) have the same intended uses.

Does the New Device Have Technological Characteristics That Raise New Types of Safety and Effectiveness Questions?

There are no new technology characteristics. The Gemini Bonded Sterilization Wrap incorporates the same design features and principles of operation found in currently marketed product.

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This product modification involving the subject and predicate devices does not significantly alter the Gemini Wrap or raise questions regarding safety or effectiveness.

Information within this Premarket Notification demonstrates that there are no significant differences in technological characteristics between Medline's Gemini Bonded Sterilization Wrap and the cited predicate device.

Summary of Non-Clinical Testing

Table 1 - Summary of Performance Testing

Test Objective	Testing Standards	Performance Results
Primary Skin Irritation Testing	ISO 10993-10	Meets ISO Requirements
Microbial Barrier Properties	ISO 11607-1 ASTM F1980	Meets ISO and ASTM Requirements

The safety and effectiveness of Medline's Gemini Bonded Sterilization Wrap is adequately supported by the substantial equivalence information, materials information, and Design Control activities referenced within this Premarket Notification.

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Gemini Bonded Sterilization Wrap is as safe, as effective, and performs as well as the predicate device [Gemini Sterilization Wrap (K113353)].